K091676

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Official Contact: Ronald Dudek – Director of Quality

Proprietary or Trade Name: Models – MC-245, MC-246, MC-247, MC-341, MC-343, MC-344

Common/Usual Name: Clinical electronic thermometer

Classification Name/Code: FLL – clinical electronic thermometer
21 CFR 880.2910

Device: Models – MC-245, MC-246, MC-247, MC-341, MC-343, MC-344

Predicate Devices: Omron – MC-3B – K881446

Device Description:
These are simple electronic thermometer which is a thermistor to measure temperature.

- All the functions, except posture symbol, are the same as the predicate device, MC-3B, K881446.
- Power source – battery operated
- Calculation method (system) is the same and identical to the predicate, K881449

The differences between the various models are:

- Some models have a flexible or rigid or rigid / flexible tip
- Offered with a probe cover
- Temperature scale offered in C° & F° or F° only
- Readout time is different

Indications for Use:
The Omron electronic thermometer Models MC-245, MC-246, MC-341, MC-343, and MC-344 are intended to measure the body temperature either oral, axillaries (under arm) and rectal and Model – MC-247 measure the body temperature oral (basal) and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.

Environment of Use: Clinics, hospital and home environments

Contraindications: None

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Summary of substantial equivalence

	MC-3B K881446	MC-245/246/247 MC-341/343/344
Measurement Method	Human temperature is detected by thermistor and calculated	Human temperature is detected by thermistor and calculated
Display	Reading value is displayed on LCD with 4 digits.(0.1 increments)	Reading value is displayed on LCD with 4 digits.(0.1 increments)
Buzzer	Beeper sound at peak temperature	Beeper sound at peak temperature
Power Source	Battery(LR41 type)	Battery(LR41 type)

SPECIFICATION	MC-3B K881446	MC-245, MC-246, MC-247 MC-341, MC-343, MC-344
Display	LCD Digital Display	LCD Digital Display
Measurement Range	89.6 ˚F to 107.6 ˚F	89.6 ˚F to 107.6 ˚F, 32.0 ˚C to 42.0 ˚C These models switch the display unit (˚F, ˚C) alternately.
Measurement area	Oral, rectum, under arm	Oral, rectum, under arm, except Model MC-247 is for oral (basal) only
Accuracy	±0.2 ˚F	±0.2 ˚F, ±0.1 ˚C
Display Resolution	4 Digits (0.1 ˚F increments)	4 Digits (0.1 ˚F / 0.1 ˚C increments)
Weight	Approx.1/3 oz /(11g)	Approx.1/3 oz / (11g)
Length	Approx. 130mm	Approx. 130mm
Battery	1 each LR41 Alkali 1.5V D.C	1 each LR41 Alkali 1.5V D.C
Battery Life	Approx. 300 hours. (Continuous use)	Approx. 2 years (3 times measurements / day)
Ambient Temperature for use	50 ˚F to 104 ˚F (10 ˚C to 40 ˚C)	50 ˚F to 104 ˚F (10 ˚C to 40 ˚C)
Ambient Temperature for storage	4 ˚F to 140 ˚F (-20 ˚C to 60 ˚C)	4 ˚F to 140 ˚F (-20 ˚C to 60 ˚C)
Ambient Humidity for use	30 to 85%RH	30 to 85%RH
Ambient Humidity for storage	30 to 95%RH	10 to 95%RH

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Differences Between Other Legally Marketed Predicate Devices

The Omron thermometer models MC-245, MC-246, MC-247, MC-341, MC-343, and MC-344 are viewed as substantially equivalent to the predicate device because:

Indications –
- Identical to predicate – K881446

Technology –
- Identical algorithms and means of measuring temperature to predicate – K881446

Operating specifications –
- Identical to predicate – K881446

Materials –
The materials have been tested in accordance to ISO 10993.

Environment of Use –
- Identical to predicate – K881446

Patient Population –
- Identical to predicate – K881446

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Omron Healthcare, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

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Re: K091676
Trade/Device Name: Omron Thermometer Models MC-245, MC-246, MC-247, MC-341, MD-343, MC-344
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 25, 2009
Received: July 29, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 091676 (To be assigned)

Device Name: Omron Thermometers
Models MC-245, MC-246, MC-247,
MC-341, MC-343, MC-344

Indications for Use:

The Omron electronic thermometer Models MC-245, MC-246, MC-341, MC-343, and MC-344 are intended to measure the body temperature either oral, axillaries (under arm) and rectal and Model – MC-247 measure the body temperature oral (basal) and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.

Prescription Use __ (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use XX** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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